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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,855	06/22/2001	Dirk M. Anderson	2883-US	8635

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,855	ANDERSON, DIRK M.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21,23-28 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21,23-28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicants' Amendment and Response to office action dated January 16, 2004 filed on July 19, 2004 is acknowledged. Claims 1-13 have been canceled. Claims 14, 17, 24, 30-33 have been amended. Claims 22 and 29 are withdrawn from the prosecution. Therefore, claims 14-21, 23-28 and 30-33 are currently pending and are under examination.

Response to Arguments and Remarks

Restriction Election:

In response to Applicants' request for a clarification regarding the status of claims 22 and 29, it should be noted that these claims further require a restriction because the method is *in vivo* in claims 22 and 29 and patentably distinct from the other method claims. Therefore, they are treated as a separate patentable invention and not as a distinct species.

Priority:

In response to the reasons given in pages 5-6 of the 'Amendment and Response' this application is entitled to the benefit of the December 23, 1998 filing date of the provisional application 60/113,820.

Rejection under *35 USC § 112, Second Paragraph:*

Rejection of claims 16 and 26 as being indefinite because of the phrase "one or more" is withdrawn in light of remarks at page 9 of the 'Amendment and Response.'

Rejection of claims 30 and 31 being indefinite as to the biological activity, sequence and physical characteristics of the fragments is withdrawn in light of remarks at page 9 of the 'Amendment and Response.'

Rejection of claims 32 and 33 is withdrawn in light of Applicants' remarks on page 9-10.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-33 stand/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting binding between a ss3939 polypeptide and a binding partner of said ss3939 polypeptide, does not reasonably provide enablement for all the soluble proteins, and fragments or mutants generated from any position located on the sequence of the ss3939 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification has disclosed a method for inhibiting binding between ss3939 polypeptide and a binding partner of said ss3939 and variants thereof, wherein the binding partner is expressed by human umbilical vein endothelial cells. There is no guidance as to how the functional fragments and mutants of the claimed ss3939 protein can be generated. The specification has provided no guidance to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein, which are tolerant to change (e.g. by amino acid deletions, insertions or substitutions), and the nature and extent of changes that can be made in these positions. Although the specification outlines generic procedures for producing and screening for protein variants, this is not adequate guidance as to the nature of specific active derivatives that may be constructed. Given the lack of teachings or guidance in applicants' disclosure regarding the variants of soluble protein other than the one specifically referenced Fc fusion protein, such as ss3939/Fc described in Examples 2 and 5, it would require undue experimentation by one skill in the art to make mutants/fragments of ss3939 polypeptide or other undefined molecules having an activity substantially equivalent to that of ss3939 polypeptide, commensurate in scope with the claims.

Further, Applicants have stated at page 7 that the soluble ss3939 have C-type lectin (carbohydrate binding domain) and are expected to have the same property of binding to human umbilical vein endothelial cells. Applicants have provided Exhibit 1 and 2 as examples of the

knowledge in the prior art and the level of skill of those in the art regarding C-type lectins. Exhibits 1 and 2 have been reviewed but the molecular model of the carbohydrate binding domain in rat mannose-binding protein (MBP) (Exhibit 1) and its sequence comparison with C-type lectin domains from human E-selectin, rat macrophage lectin (ML) and with SEQ ID NO: 2 of instant application (Exhibit 2) are not sufficient to enable those of skill in the art to practice the claimed invention. Only by having a carbohydrate binding domain, the soluble ss3939 cannot have the similar function as the C-type lectin proteins. Thus, without knowing the function of a soluble polypeptide ss3939 variants it would require undue experimentation to make variants that are at least 90% or 95% identical to amino acids 22-through 227 of SEQ ID NO: 2 and that bind to human umbilical vein endothelial cells. Undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 14, 24, 30 and the dependent claims thereto are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Bringing the polypeptide to the contact of a binding partner, for example contacting of an endogenous ss3939 to the cells expressing surface binding partners; inhibition of binding step; and the ultimate biological effects that result from inhibiting ss3939 polypeptide binding with a binding partner. Claims 15-21, 23, 25-28 and 31-33 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claims from which they depend upon.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30, 31, 32 and 33 are rejected under 35 USC 102 (e) as being anticipated by Komatsoulis et al. (US 6476195, priority claimed July 30, 1998, issued November 5, 2002). Komatsoulis et al. teach a human secreted protein, wherein the invention relates to screening method of identifying binding partners of polypeptides of said protein (see abstract, summary of invention in col 1-2). The reference teaches a cDNA clone that encodes a novel polypeptide molecule, designated as "HOEEU24", having amino acid residues 1-374 of SEQ ID NO: 166 encoded by Gene 40 (Table 1, see col 173, 174). The polypeptide of this gene has a transmembrane domain and shares structural features to type Ia membrane proteins (col 74 and 75) having 99.1% sequence identity to amino acids 22-227 of SEQ ID NO: 2 (see sequence alignment result, Rosen et al. "98 Human Secreted Proteins", Database: A_Geneseq_19June03, Accession NO: US-09-489-847-166, Patent 6476195, earlier filing date: July 30 1998). This reads on claims 30 and 31 of instant application where soluble polypeptide has 90% (claim 30) and 95% (claim 31) sequence identity to amino acids 22-227 of SEQ ID NO: 2. Further the amino acid sequence alignment result also indicates 20 contiguous amino acids of SEQ ID NO: 2 (claim 30). The sequence alignment also indicates 2 amino acid residues substitution (xaa denotes any of the naturally occurring L-amino acids) when compared to amino acids 22-227 of SEQ ID NO: 2, anticipating claim 32 where polypeptide has from one to ten deletions, insertions or substitutions of amino acid residues when compared to amino acids 22 through 227 of SEQ ID NO: 2. The sequence alignment also indicates 2 conservative substitutions of amino acid residues Lys at position 63 and Ala at position 91 when compared to amino acids 22 through 227 of SEQ ID NO: 2, anticipating claim 33 where the polypeptide has from one to ten conservative substitutions of amino acid residues when compared to amino acids 22 through 227 of SEQ ID NO: 2. The

polypeptide is considered for having a conservative substitution at position 63 Lys substituted with Arg and at position 91 Ala substituted with Ile, val or Leu, thus anticipating claim 33. Thus claims 30-33 are anticipated by Komatsoulis et al.

Conclusion

No claims are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette,1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.

Rita Mitra, Ph.D.
September 23, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER